

Memorandum



Subject

Internet Presentation with McKesson Corp. on September 1,
2005
(DFN: 060-06.05)

Date

OCT 20 2005

To

Joseph Rannazzisi
Acting Deputy Assistant Administrator
Office of Diversion Control

From

5/
Michael R. Mapes, Chief
E-Commerce Section (ODC)

On September 1, 2005, a meeting was held at the Office of Diversion Control conference room. In attendance were Mr. John Gilbert, Legal Counsel, Ronald Bone, Senior Vice President, Distribution Support, Gary Hillard, Director of Regulatory Affairs, Michael R. Mapes, Chief, E-Commerce Section, Charles E. Trant, Office of Chief Counsel, Diversion & Regulatory Litigation Division, Jim Crawford Office of Diversion Control, and Kyle J. Wright, Chief, E-Commerce Operations Unit. The purpose of the meeting was to address the illegal domestic Internet pharmacy problem and their source of supply.

Mr. Mapes opened the meeting by presenting to the representatives of McKesson Corp. a power point briefing which explained the common characteristics of Internet pharmacies and why their activities are illegal. Reviewed with the representatives of McKesson Corp. were:

- Supreme Court Cases and Immediate Suspension orders of Internet pharmacies.
- Establishing the medical need necessity for a prescription to be legal.
- The DEA Internet Policy.
- Verified Internet Pharmacy Practice Sites (VIPPS).
- Policies published by the American Medical Association (AMA) and the Federation of State Medical Boards.
- Review of the suspicious order requirements Title 21, Code of Federal Regulations.
- Common practices and ordering patterns of Internet pharmacies.

After the presentation, Mr. Mapes presented to representatives of McKesson Corp. specific customers of McKesson Corp., who have ordered substantial quantities of hydrocodone products. These specific customers of McKesson Corp. were:

- United Prescription Services
- Ninth Avenue Pharmacy

Mr. Mapes finalized the presentation by advising the representatives of McKesson Corp. that they needed to thoroughly review the materials which had been presented to them and review in-depth the purchasing patterns and quantities of their customers. Representatives of McKesson Corp. acknowledged understanding of the material presented.



In consultation with Mr. Trant, it was agreed, that if E-Commerce Operations (ODCO) were to identify a highly suspicious pharmacy to which McKesson Corp. was the wholesaler, ODCO would notify McKesson Corp. via e-mail of the suspicious activity for McKesson Corp. to review and take the actions the company deems appropriate. Mr. Mapes also informed the representatives of McKesson Corp., if he desired further information, or training, to notify ODCO which would provide the requested information or training.


The meeting between McKesson Corp. and DEA was ended at this time, with each party having a clearer understanding and agreement as to how best address the sources of supply to Internet pharmacies.

Attachments:

1. Briefing Binder
2. Material on McKesson Corp. Customers

bcc: ✓ DFN: 060-06.05
Chron

ODC

ODCO  :KWright:pln:703-653-2103:10/21/05

Filename: McKesson.doc

INTERNET PHARMACY DATA

Meeting with
McKesson Corporation
DEA Headquarters
September 1, 2005

Internet Pharmacies

- Domestic Based
 - Related to an existing pharmacy
 - Walk in patients with prescriptions
 - Some legitimate some not
 - Unrelated to brick and mortar pharmacy
 - No local patients or doctors
 - No walk-in business
- Foreign based

Involved With Internet Pharmacies

- Doctors
- Pharmacies
- Distributors
- Internet Service Providers
- Credit Card Companies
- Delivery Services
- Internet Pharmacy Facilitators

ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor

DEA DISTRIBUTOR REGISTRATIONS

- Title 21 United States Code, Section 823
 - Is the registration in the public interest?
 - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
 - Mail order sales to doctor
 - Most sales were Morphine
 - Increase in quantities purchased
 - Business practices attracted customers who were violating the law
 - Drugs have inherent susceptibility to harmful and illegal use

EZ RX, LLC

- 69 FR 63,178 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 300,000 dosage units in three months
 - Phentermine, Phendimetrazine, Ambien

RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 19,300,000 dosage units of various controlled substances
 - Based on Internet Questionnaires
 - Not in the course of professional practice

Supreme Court Case

- United States v. Moore
423 U.S. 122 (1975)
 - Usual course of professional practice
 - Patient with a Medical Complaint
 - History
 - Physical Examination
 - Nexus Between Complaint/History/Exam and Drug Prescribed

DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

VIPPS

- National Association of Boards of Pharmacy
 - Licensed, legitimate, Inspection
 - Verified Internet Pharmacy Practice Sites
 - 14 VIPPS Approved Pharmacies as of 06-27-2005
 - www.nabp.net/vipps/consumer/faq.asp

American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
 - valid patient-physician relationship, includes, but not limited to:
 - History and physical exam
 - Dialogue with patient
 - Follow up to assess outcome
 - Maintain medical record
 - Include electronic prescription in patient's medical record

Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
 - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
 - Treatment based solely on an online questionnaire is not acceptable

Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate system to identify suspicious orders
- Report suspicious orders to DEA when discovered

Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

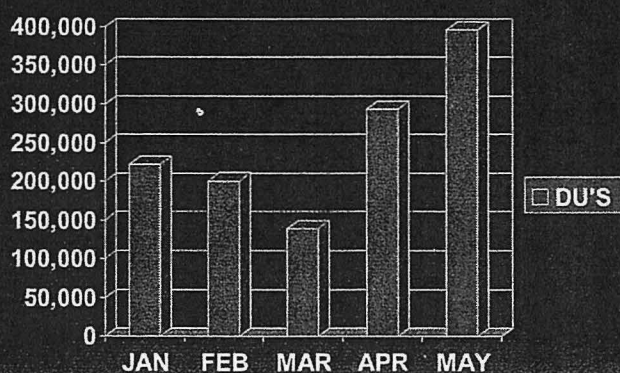
Suspicious Orders

- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision

Example #1

- Retail pharmacy
 - Quantities of drugs
 - Range of drugs sold – only Phentermine
 - % controlled and % non-controlled
 - Size of orders over time
 - Location of store

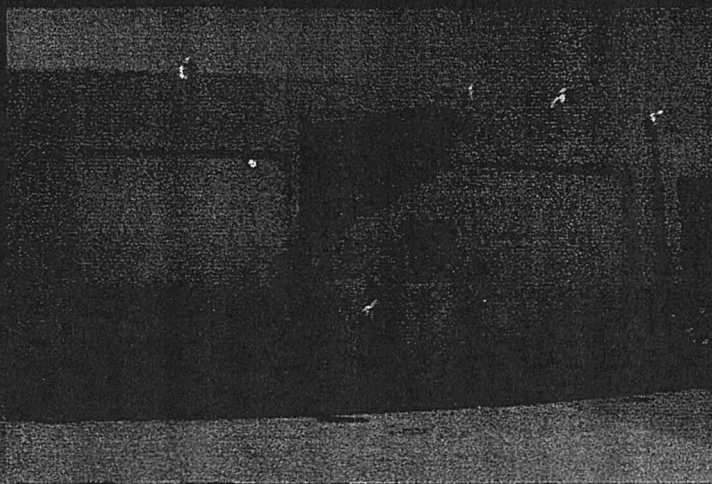
Example #1



Example #2

- Retail Pharmacy
 - Location of store
 - Only Hydrocodone and Alprazolam
 - Very large quantities
 - FedEx boxes for delivery

ANOTHER PHARMACY

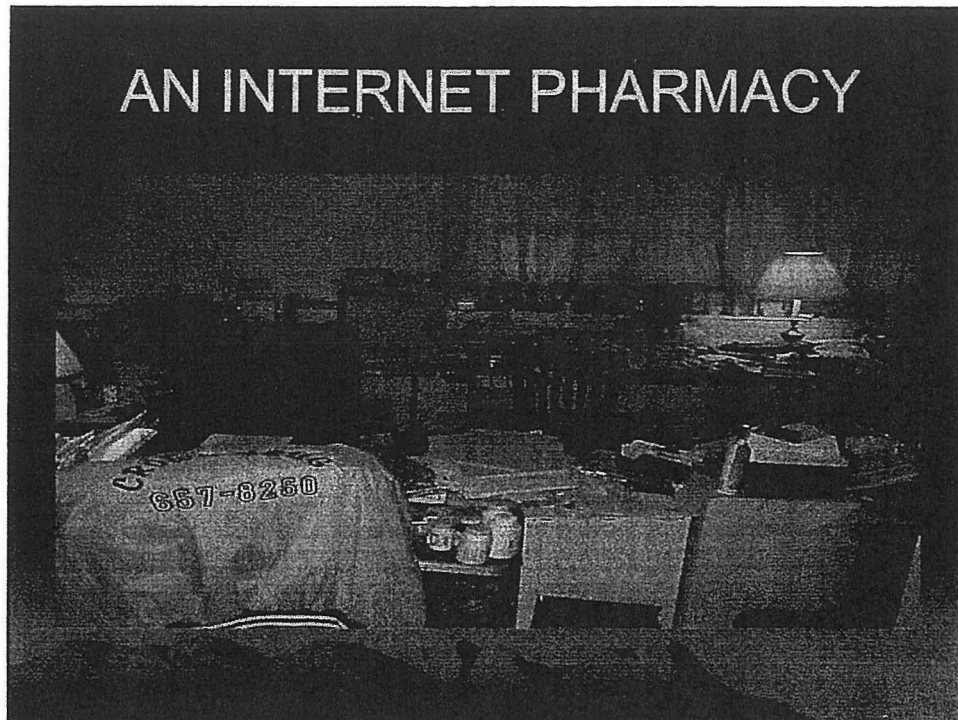




Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

AN INTERNET PHARMACY



SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharmacies

SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

SUMMARY

- DEA will:
 - Meet with other distributors involved in distributing to Internet pharmacies
 - Provide this information to your employees at your request
 - Meet with Industry groups or associations to discuss issue if requested

Contact Information

Michael Mapes
Chief, E-Commerce Section
703-653-2048

Kyle Wright
Chief, E-Commerce Operations Unit
703-653-2103

